IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. Of: SMITS ET AL

Filed: AUGUST 30, 2001

For: FRACTIONATED POLYDISPERSE COMPOSITIONS

Group: 1623

Examiner: H. OWENS, JR. DOCKET: MALD RAFF .16 CON2

Assistant Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Dear Sir:

This is a continuation application under 37 CFR 1.53(b) of prior non-provisional application No. 08/765,874 filed on May 27, 1997. Prior non-provisional application 08/765,874 received a Notice of Allowance on May 11, 2001. The issue fee was paid on August 13, 2001.

In this continuation application claims 1-29 are presented for examination. Applicants wish to note as follows.

Claims 1-10 relate to the process for producing a fractionated polydisperse inulin composition from a native polydisperse inulin which involves, among other things, a rapid achievement of a high degree of super saturation obtained by bringing the native inulin into solution in water at a temperature above 85°C and by a rapid cooling by a heat exchanger to a temperature between -6°C and 40°C at a rate between 0.2°C and 10°C/sec, or by rapid concentration increase through evaporation of the solution, or by combination thereof, to provide said fractionated polydisperse inulin the form of particles followed by separation of the particles obtained after crystallization and washing of the separated particles with water to provide said

fractionated polydisperse inulin composition. Said fractioned polydisperse inulin composition is said to have an average degree of polymerization which is double or higher than the average degree of polymerization of said native polydispersed inulin, containing less than 0.2 wt % monomer and which does not contain any detectable amount of alcohol. Dependent claims 2-10 properly scope claim 1. Support can be found at p. 9, l. 20-36; p. 15, l. 14-32; p. 16, l. 35 to p. 17, l. 17; p. 19, l. 10 to p. 20, l. 1; and p. 22, l. 19 to p. 23, l. 12.

Applicants therefore respectfully submit that claims 1-10 of this continuation application properly scope and are consistent with the allowable subject matter of the parent case, U.S. Application No. 08/765,874 and allowed claims 27-29, 37-40, 42, and 48 therein.

Applicants herein also present product claims 11-29. Applicants note as follows. In the parent application 08/765,874, and prior to that point in the prosecution where the product claims where removed from consideration by the Applicants so that the process claimed therein could pass to issue, the Examiner had rejected the composition claims on the grounds that the prior art disclosed delta inulin according to the Merck Index (pg.660, compound No. 4865). See Office Action of March 20, 2000.

Applicants would again like to address the Examiner's remarks regarding "delta" inulin. Applicants note that the invention herein relates to a non-chromatographically fractionated polydisperse carbohydrate composition having four important characteristics in the product, i.e.:

1. an average degree of polymerization which is double or higher than the average degree of polymerization of native polydispersed carbohydrate.
2. containing less than 0.2 wt % monomer and less than 0.2 wt % dimers and less than 1.5 wt % oligomers.
3. containing less than 0.2 wt % ash; and

4. no detectable amounts of alcohol.

Applicants therefore trust that the Examiner can appreciate that the issue regarding the exact physical form of inulin (delta inulin being a spherical crystal) is not the distinguishing feature of the invention advanced herein by Applicants. Accordingly, the reliance of the Examiner on the Merck Index remains elusive to the Applicants and it is not seen how this is relevant nor supportive of a rejection under 35 USC 102/103.

Applicants therefore respectfully submit that the Merck Index does not disclose, teach or suggest the various compositional features of Applicant's composition claims.

The other reference relied upon by the Examiner, Mitchell (US Patent No. 4,285,735) can therefore be quickly considered and distinguished. At page 4 of the Office Action of June 22, 1999 in the parent case, the Examiner noted that "with regard to the carbohydrate compositions, Mitchell discloses crystalline inulin but is silent with regard to the polydispersity, average DP, monomer and dimmer content, oligomer content, ash content, alcohol content, crystalline shape and crystalline diameter." As the Examiner has correctly noted that Mitchell does not disclose, teach or suggest the compositional features of Applicant's claims it is respectfully submitted that claims 11-29 recited herein are in condition for allowance.

Accordingly, in view of the lack of teaching in the Merck Index and/or Mitchell taken alone or in combination with each other, of a carbohydrate with all of the characteristics of the composition of the present invention, the composition of the invention as recited herein has to be considered as novel and non-obvious in view of Mitchell in combination with the Merck Index.

Finally, Applicants note that in the Office Action of June 22, 1999, the Examiner made the additional comment that Applicants' claimed non-chromatographically fractionated polydisperse carbohydrate composition having the specific characteristics noted above would

necessarily be obvious since "the art of chemical separations is so advanced that the artisan is certainly capable of using HPLC to size fractionated inulin into the desired polydispersity prior to crystallization." Applicants respond as follows:

Applicants are unaware of authority which supports a rejection under 35 USC § 103 on the grounds of an Examiner's high level confidence in the capability of any particular instrument to achieve the compositional features of a product claim. Certainly, Applicants understand and acknowledge that HPLC is a known chromatographic technique. However, it is respectfully submitted that 35 USC § 103 does not allow an Examiner's assessment in HPLC capabilities, no matter how high, to serve as grounds of an obviousness rejection.

At its core then, Applicants remain confronted with the existence of HPLC and the Examiner's suggestion that HPLC would have been an obvious vehicle to attempt the preparation of the fractionated disperse carbohydrate composition of the present invention. However, "obvious to try" has long been held not to constitute obviousness. In re Thomas F. Deul et al, 51 F.3rd, 1552; 34 USPQ 2nd, 1210 (CAFC 1995). As correctly noted by the Federal Circuit therein, "A general incentive does not make obvious a particular result nor does the existence of techniques by which those efforts can be carried out." 51 F.3d at 1559. Accordingly, it is respectfully submitted that the Examiner's suggestion that the non-chromatographically fractioned polydisperse carbohydrate composition of claim 11 would be obvious based on the grounds that it would be obvious to try HPLC is believed respectfully traversed.

Applicants trust that they have addressed all of the outstanding objections/ rejections to the claims and the application herein is in condition for allowance. Allowance at an early date is solicited.

In the event there are any fee deficiencies or additional fees are payable, please charge them (or credit any overpayment) to our Deposit Account No. 08-1391.

Respectfully submitted,

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Signature of Person Mailing Carol McClelland

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